K061853

AUG 18 2006

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Grace Medical Adjustable Length and Fixed Length Partial and Total Ossicular Replacement Prostheses

Trade Name: The family of Grace Medical Adjustable and Fixed Length Partial & Total Ossicular Replacement Prostheses consists of:

- Grace Medical ALTO (Adjustable Length Total Ossicular) Prostheses
- Grace Medical ALPO (Adjustable Length Partial Ossicular) Prostheses
- Grace Medical FLTO (Fixed Length Total Ossicular) Prostheses
- Grace Medical FLPO (Fixed Length Partial Ossicular) Prostheses
- Silverstein ALTO (Adjustable Length Partial Ossicular) Prostheses with Footplate Tack
- Grace Medical Frisbee Myringopexy (Fixed Length Partial Ossicular) Prostheses

Common Name: Partial Ossicular Replacement Prostheses
Total Ossicular Replacement Prostheses

Classification Name: Partial Ossicular Replacement Prostheses (CFR 21 § 874.3450)
Total Ossicular Replacement Prostheses (CFR 21 § 874.3495)

Official Contact: Jeff Cobb
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Date Prepared: June 30, 2006

Predicate Devices – The Grace Medical Adjustable Length and Fixed Length Partial and Total Ossicular Prostheses are substantially equivalent to the predicate devices listed below.

Predicate Device	Manufacturer	510(k) Number (if known)
BELL Prostheses (Various Models)	Heinz Kurz GmbH	K972492
AERIAL Prostheses (Various Models)	Heinz Kurz GmbH	K972585
Length-Adjustable Partial (BELL Vario) and Total (AERIAL Vario) Ossicular Prostheses	Heinz Kurz GmbH	K990923
Smith & Nephew PORP & TORP	Gyrus ENT	K002737
Smith & Nephew Off-Centered PORP	Gyrus ENT	K002464
Gyrus ENT Brackman Modified TORP	Gyrus ENT	?

Intended Use – The Grace Medical Adjustable Length and Fixed Length Partial & Total Ossicular Replacement Prostheses have the same primary intended use as the predicate devices.

An ossicular replacement prosthesis is a device intended to be implanted for the functional reconstruction of segments of the ossicular chain and facilitates the conduction of sound wave from the tympanic membrane to the inner ear.

Ossicular replacement prostheses are indicated for the functional restoration of the ossicular chain when a conductive hearing loss is present. Indications for use include: Chronic middle ear disease, Otosclerosis, Congenital fixation of the stapes, Secondary surgical intervention to correct for a significant and persistent conductive hearing loss from prior otologic surgery, and surgically correctible injury to the middle ear from trauma.

Materials – The Grace Medical Adjustable Length and Fixed Length Partial & Total Ossicular Replacement Prostheses are manufactured from the same or similar materials as the predicate devices. The Grace Medical Adjustable-Length PORP's and TORP's contain a medical grade silicone sleeve fixed to the titanium shaft which allows for adjustment to length by the user.

Design Features – Various designs of Grace Medical Adjustable Length and Fixed Length Partial & Total Ossicular Replacement Prostheses are available to meet physician preference. The design features of the Grace Medical Adjustable Length and Fixed Length Partial & Total Ossicular Replacement raise no new safety or effectiveness issues.

Comparison Charts

	GRACE MEDICAL ADJUSTABLE LENGTH AND FIXED LENGTH PORPS & TORPS	GRACE MEDICAL PARTIAL & TOTAL PROSTHESES (K972815)	BELL PROSTHESES KURZ (K972492)	AERIAL PROSTHESES KURZ (K972585)	VARIO LENGTH-ADJUSTABLE PROSTHESES KURZ (K990923)	SMITH & NEPHEW PORP & TORP GYRUS ENT (K002737)	SMITH & NEPHEW OFF-CENTERED PORP GYRUS ENT K002464)	GYRUS ENT BRACKMAN MODIFIED TORP GYRUS ENT (KXXXXXX)
Intended Use	Total and Partial Reconstruction of the Ossicular Chain	Total Partial Reconstruction of the Ossicular Chain	Partial Reconstruction of the Ossicular Chain	Total Reconstruction of the Ossicular Chain	Total and Partial Reconstruction of the Ossicular Chain	Total and Partial Reconstruction of the Ossicular Chain	Partial Reconstruction of the Ossicular Chain	Total Reconstruction of the Ossicular Chain
Head Material(s)	Titanium (Titanium Alloy) Hydroxylapatite (HA) HA-Coated Ti Stainless Steel Silicone	Titanium (Titanium Alloy) Hydroxylapatite Otosil (Silicone w/ $BaSO_4$) Polyethylene PTFE Stainless Steel Silicone	Titanium	Titanium	Titanium	Titanium (Titanium Alloy)	Hydroxylapatite	Plasti-pore
Shaft Material(s)	Titanium (Titanium Alloy) Ti w/Silicone Sleeve PTFE Stainless Steel Polyethylene Silicone	Titanium (Titanium Alloy) Polyethylene PTFE Silicone	Titanium	Titanium	Titanium	Titanium (Titanium Alloy)	Titanium (Titanium Alloy)	Plastipore w/ wire
Head Shape	Circular Semi-circular Oval Oblong Notched	Circular Trapezoidal Oval Notched	Circular	Circular	Circular	Circular	Oval	Round
Functional Length (mm)	Fixed Sizes from 0.5 to 9.0 Adjustable model – Trimmed to length Intraoperatively	4.0 to 8.0	1.75 to 4.50	3.0 to 7.0	Adjustable model – Trimmed to length Intraoperatively	2.0 to 9.0 TORPs are Trimmed to length - Intraoperatively	Unknown	8mm Trimmable
How Supplied	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile

Differences between the Grace Medical Modified Partial Ossicular Replacement Prostheses and the predicate devices should not raise new issues regarding safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 18 2006

Grace Medical, Inc.
c/o Mr. Jeff Cobb
8500 Wolf Lake Dr., Suite 110
Memphis, TN 38133

Re: K061853
Trade/Device Name: Grace Medical Adjustable and Fixed Length Partial & Total Ossicular Replacement Prostheses
Regulation Number: 21 CFR 874.3450
Regulation Name: Partial Ossicular Replacement Prostheses; Total Ossicular Replacement Prostheses
Regulatory Class: II
Product Code: ETB; ETA
Dated: June 30, 2006
Received: July 18, 2006

Dear Mr. Cobb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K061853
Device Name:

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- **Silverstein ALTO (Adjustable Length Partial Ossicular) Prostheses with Footplate Tack**
- **Grace Medical Frisbee Myringopexy (Fixed Length Partial Ossicular) Prostheses**

a) Indications for Use

An ossicular replacement prosthesis is a device intended to be implanted for the functional reconstruction of segments of the ossicular chain and facilitates the conduction of sound wave from the tympanic membrane to the inner ear.

Ossicular replacement prostheses are indicated for the functional restoration of the ossicular chain when a conductive hearing loss is present. Indications for use include:

(a) Chronic middle ear disease,
(b) Otosclerosis,
(c) Congenital fixation of the stapes,
(d) Secondary surgical intervention to correct for a significant and persistent conductive hearing loss from prior otologic surgery, and
(e) Surgically correctible injury to the middle ear from trauma.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2/96)

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number